340B Drug Pricing Program
Results of a Survey of Eligible but Non-Participating Rural Hospitals

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Executive Summary

The 340B Drug Pricing Program (hereafter referred to as the 340B program) enables certain types of safety-net organizations to obtain deeply discounted outpatient medications at prices below the "best price" typically offered to Medicaid agencies. In the past, few rural hospitals qualified, but as a result of the Medicare Modernization Act of 2003 (MMA), many more rural hospitals are potentially eligible to participate.

This working paper summarizes the results of a 2006 survey of pharmacy directors at rural hospitals eligible to participate in the 340B program but identified as not participating at the time of the survey. The purpose of this study was to understand why rural hospitals that are eligible for the program are not participating and to determine whether there are specific program features that present barriers to participation. A companion survey of hospitals currently participating in the program was also conducted; findings will be released in a separate report.

Pharmacy directors of 240 rural hospitals in 36 states identified as eligible but not participating in the 340B program as of April 1, 2006, were surveyed by mail to examine their awareness of the 340B program and to understand their reasons for not participating. The survey response rate was 39.2%. The results show that awareness of the 340B program among eligible rural hospitals is still limited, with over half of the respondents unaware they were eligible to participate. While comprehensive information on the 340B Drug Pricing Program is available from federal agencies, most notably the Health Resources and Services Administration's Office of Pharmacy Affairs which administers the program, respondents relied instead on peers from other hospitals or staff within their own hospital to learn more about the program.

A solid understanding of the program is necessary to evaluate the expected cost savings and implementation requirements when considering whether or not to participate in the 340B program. Over three-quarters of the respondents who knew they were eligible to participate had not sought technical assistance to determine if program participation would be beneficial to their hospital. However, 71% reported the need for such assistance, with the most common focal areas being maintaining separate inpatient and outpatient records (66%), understanding 340B drug pricing (54%), and conducting a cost-benefit analysis (48%).

Additional efforts are needed to ensure that rural hospital administrators are aware of their eligibility to participate in the 340B program. Targeted education and technical assistance would help to ensure that pharmacy directors and administrators understand the program and are able to make informed decisions about whether or not to participate.

Introduction

The 340B Drug Pricing Program (hereafter referred to as the 340B program) enables certain types of safety-net organizations to obtain deeply discounted outpatient medications at prices below the "best price" typically offered to Medicaid agencies. Participating organizations have reported savings of 25-50% on covered outpatient-drugs.[1] Eligible safety-net organizations include, among others, public or private non-profit general acute care hospitals with a Medicare Disproportionate Share Hospital (DSH) adjustment percentage greater than 11.75% that are paid under the Prospective Payment System (PPS).[i] In the past, few rural hospitals qualified, but as a result of the Medicare Modernization Act of 2003 (MMA), many more rural hospitals are potentially eligible to participate. The MMA has made it easier for rural hospitals with fewer than 500 acute care beds to meet the greater than 11.75% DSH adjustment threshold by applying the same formula as the one used for large urban hospitals.[2] With the changes made by the MMA, almost 400 of the over 950 rural non-profit or government-owned PPS hospitals are now eligible to participate in the 340B program. Of these, just fewer than 150 were participating at the time of this study.

Even with the potential for significant cost savings, there are some barriers to program implementation and other considerations that may influence administrators' decisions on whether or not to participate in the program. The pricing of outpatient drugs available through the 340B program is proprietary information, and the lack of availability of this information makes it difficult for administrators to determine the costs and benefits of participation. Also, the 340B program is limited to non-profit hospitals

[i] Critical access hospitals are not eligible for the 340B program as they are not paid under PPS and are not eligible for DSH payments.

that serve low-income individuals and requires non-governmental hospitals to have a contract with the state or local government to provide indigent care. Establishing these agreements with state or local governments may be challenging.

The 340B program also affects how pharmacy staff purchase, track, and administer their drug inventory. Hospital administrators must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO), which, for those that purchase other goods through such organizations, may affect the discount received from a GPO if the discount is based on the total volume of purchased goods.[3] Outpatient drugs may not include any medications paid for as part of inpatient services, so separate records for inpatient and outpatient drugs are required. Participating hospitals must also keep records of Medicaid patients who receive 340B covered drugs to ensure that pharmaceutical companies are not providing duplicate drug discounts through both the 340B program and the Medicaid national rebate program. Finally, only patients of participating hospitals may receive drugs purchased through 340B. According to the Health Resources and Services Administration (HRSA), patients who can obtain drugs through the program are defined as follows:

> *1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity. An individual will not be considered a ``patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.* [4]

Because a person is not considered a patient if the only service provided is dispensing medication, hospitals with retail pharmacies must have tracking systems that can distinguish between customers whose only contact with the hospital is to fill a prescription and those who are also patients as defined by criteria 1 and 2 above.

This working paper summarizes the results of a 2006 survey of pharmacy directors at rural hospitals eligible to participate in the 340B program but identified as not participating at the time of the survey. The purpose of this study was to understand why rural hospitals that are eligible for the program are not participating and to determine which specific program features presented barriers to participation. Respondents were surveyed by mail to examine their awareness of the 340B program and to understand their reasons for not participating. A companion survey of administrators at hospitals currently participating in the program was also conducted; findings will be released in a separate report. Information in this report describes the characteristics of eligible but non-participating hospitals, if and how hospital pharmacy directors learned they were eligible to participate, the availability and use of technical assistance, and key factors that inform decisions on whether or not to participate in the 340B program.

Methods

The North Carolina Rural Health Research and Policy Analysis Center and the NORC Walsh Center for Rural Health Analysis collaborated in the design of the survey instrument. The survey was developed with information obtained from 340B program experts and telephone interviews with staff from ten hospitals that were part of the sampling frame. These hospitals were also included in the final survey.

The target population was administrators from all rural hospitals that were eligible but not participating in the 340B program. Eligible hospitals were identified from the HRSA Office of Pharmacy Affair's (OPA) *Disproportionate Share Hospitals & Their Disproportionate Share Adjustment Percentages* spreadsheet.[5] Participation status was determined based on OPA's *Covered Entity Data Extract*.[6] Hospitals in nonmetropolitan counties as identified by the US Office of Management and Budget were classified as rural for purposes of this study. Using this information, 240 rural hospitals in 36 states were identified as eligible but not participating in the 340B program as of April 1, 2006.

Pharmacy directors were identified as the hospital administrators who possessed the appropriate knowledge of their hospitals' pharmacy services and who were most likely to respond to a survey about the 340B program. These individuals were surveyed by mail to examine their awareness of the 340B program and to understand their reasons for not participating.

The initial survey was mailed to pharmacy directors at all 240 hospitals on May 1, 2006. A reminder postcard was sent to non-respondents on May 16, 2006, and second and third mailings of the survey were sent on June 1, 2006, and July 5, 2006.

Ninety-eight of the 240 surveys were returned. Of the 98 received, three surveys were returned blank and 15 were ineligible to participate in the study (eight respondents identified themselves as participating in the 340B program and seven respondents identified themselves as ineligible for the program because they were for-profit, critical access, or Indian Health Services hospitals). The remaining 80 surveys are included in the analysis below. In determining the survey response rate, it is assumed that the unknown ineligibility rate among hospitals for which no survey was returned is equal to

the known ineligibility rate among survey respondents of 15% (15/98). Under this assumption, 15%, or 204, of the 240 hospitals in the original sample would be eligible for 340B participation (and therefore for this analysis). The final survey response rate was 39.2% (80/204).

Results

When more rural hospitals became eligible to participate in the 340B program as a result of the MMA, HRSA and various professional organizations conducted outreach and offered educational sessions to help notify newly-eligible hospitals of their opportunity to participate. Despite these efforts, over half of the responding pharmacy directors (56%) were not aware their hospitals were eligible to participate in the program. It is possible that in some of these hospitals, senior leadership, such as the Chief Executive Officer or the Chief Financial Officer, had knowledge of the program but did not convey information to the pharmacy director. It is also possible that outreach organizations did not target certain hospitals because they felt that the hospital would not benefit from participation.

Respondents were queried about characteristics that might be related to their hospital's potential benefit from participating in the 340B program. While hospitals that operate in-house retail pharmacies where outpatients can have their prescriptions filled may see significant cost savings from program participation, 95% of respondents reported that their hospital does not have an in-house retail pharmacy. However, all but one reported offering services where outpatient drugs are typically dispensed (Table 1). Because of the potential for cost savings on expensive outpatient medications available

through the program, respondents were also asked to indicate whether certain types of higher cost medications that are often dispensed in an outpatient setting are dispensed at their hospital; these results are summarized in Table 2.

Table 1: Provision of outpatient services where drugs are administered (n = 80)

Service	Percent Providing (number)	Average Monthly Volume (number reporting)
Emergency department	98% (n=78)	855 visits (n=63)
Ambulatory or day surgery	86% (n=69)	55 cases (n=55)
Home health	50% (n=40)	540 visits (n=2)
Primary care clinic or rural health center	48% (n=38)	1,085 visits (n=25)
Rehabilitation clinic	18% (n=14)	391 visits (n=9)
Orthopedic clinic	16% (n=13)	145 visits (n=9)
Pediatric clinic	13% (n=10)	435 visits (n=8)
Oncology clinic	8% (n=6)	205 visits (n=5)
Pain clinic	6% (n=5)	54 visits (n=4)

Table 2: Provision of select medications (n = 80)

Drug Type	Percent Providing (number)	Average Monthly Volume (number reporting)
Aranesp or Epogen	68% (n=54)	20 doses (n=42)
Intravenous immunoglobulin	44% (n=35)	8 doses (n=28)
Remicade	38% (n=30)	3 doses (n=24)
Lupron	21% (n=17)	3 doses (n=13)
Cancer chemotherapy	20% (n=16)	17 doses (n=15)

Note: Some of these doses may be given in an inpatient setting and would not qualify for 340B pricing.

The data in Tables 1 and 2 were compared for those hospitals in which the pharmacy director knew about the 340B program and those in which the director had no knowledge of the program. Although there was a small amount of variation for each service or medication, in general, the hospitals where there was no reported knowledge of

the program appeared to be just as likely to offer the services and medications that might make participation worthwhile.

Outpatient drugs are often purchased through a hospital's group purchasing organization (GPO); however, under the 340B program, outpatient drugs may not be purchased through a GPO. To learn how program participation might affect a hospital's GPO discount, respondents were asked if their hospital participated in a GPO and what effect not purchasing outpatient drugs through the GPO might have on their overall discount. Only 6% of respondents indicated that their hospitals did not use a GPO for outpatient drug purchases. Among the 94% who did, over half did not know what the potential impact on a hospital's overall discount would be if outpatient drugs were not purchased from the GPO. The remaining respondents were evenly split between those who reported that their discount would decrease and those who reported that it would not be affected by changes in purchasing volume.

Results for the sub-set of respondents who knew they were eligible

The remainder of this working paper presents the responses of the 44% of respondents who knew they were eligible to participate in the 340B program. These individuals completed an additional series of questions that examined how they learned about the program, their technical assistance needs, and the factors influencing their decision of whether or not to participate. Hospital pharmacy directors learned they were eligible to participate in the 340B program from a variety of sources; the two most often cited were the hospital's senior administrators or corporate office (43%) and wholesalers or drug representatives (31%). Other ways administrators learned they were eligible to

participate included the following: letters from HRSA's OPA or Medicare, contact from a consultant or accounting firms, and from the pharmacy director's own research or attendance at seminars.

Once they knew their facility was eligible to participate, pharmacy directors learned more about the 340B program from a variety of sources (Table 3). Three respondents indicated that they had received no information about the program. For the remaining 32, the most common sources of information were pharmacy staff from other hospitals or their own administrators or corporate offices. Most respondents had not contacted a federal agency for information or technical assistance. Of the four who did, they all contacted HRSA's OPA, and one also contacted the Pharmacy Services Support Center. These four respondents reported that they received some or all of the assistance needed.

Table 3: Sources of program information for hospital pharmacy directors who knew they were eligible to participate (n = 35)

Information Source	Percent Obtaining Information *
Pharmacy staff from other hospitals	37%
CEO / CFO / Corporate office	34%
GPO	20%
Wholesaler or drug representative	14%
Office of Pharmacy Affairs	11%
Public Hospital Pharmacy Coalition	8%
National hospital association	6%
State hospital or pharmacy association	6%
Unspecified websites	6%
340BPVP.com (prime vendor)	3%
Consultants	3%
Other facilities	3%
Pharmacy Services Support Center	3%
Seminars	3%

* Totals greater than 100% because respondents were requested to indicate all sources they consulted.

Technical Assistance

As discussed earlier, there are challenges facing eligible hospitals in determining potential cost savings and implementing the 340B program. Pharmacy directors who knew that their hospitals were eligible were asked about the types of technical assistance they sought as well as unsolicited offers of technical assistance they received. Most (77%) had not sought any technical assistance. Of the 23% (n=8) who did seek technical assistance, the two most common areas for which assistance was requested were record keeping or inventory management (7 of 8) and cost benefit analyses (5 of 8). Assistance was usually requested from a consultant or accounting firm and was either received or the respondent plans to receive it in the future. Unsolicited offers of technical assistance were received by 31% of respondents. These offers were primarily for assistance with cost benefit analyses and record keeping or inventory management and came most often from consultants and accounting firms or wholesalers.

Pharmacy directors who knew they were eligible were also asked to identify areas in which they still need technical assistance. Ten of the 35 (29%) reported that they did not need any further assistance. Among the remaining 25 respondents, their responses indicate assistance is still needed in a variety of areas related to the 340B program (Table 4). The most commonly cited technical assistance need was for record keeping and inventory management. The next greatest need was for help in understanding 340 pricing.

Table 4: Outstanding technical assistance needs cited by pharmacy directors who knew their hospital was eligible to participate (n = 35)

Type of Technical Assistance Need Reported	Percent Indicating Need for Assistance *
Record keeping to document inpatient and outpatient drugs separately	66%
Understanding 340B drug pricing	54%
Cost-benefit analysis	48%
Tracking Medicaid drugs	46%
Indigent care contract with state or local government	34%
None	29%

* Totals greater than 100% because respondents were requested to indicate all assistance needed.

Cost Benefit Analysis

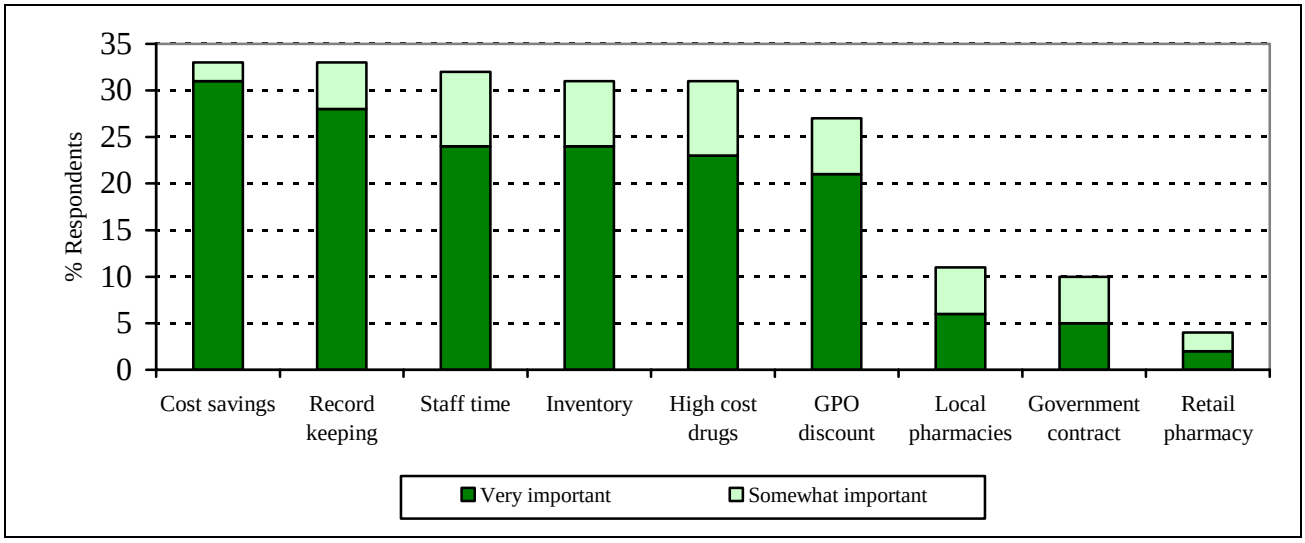
An individual hospital's potential for cost savings depends on the services offered, the type and volume of outpatient drugs administered, and prices paid for those pharmaceuticals. Only three respondents who knew they were eligible had conducted a cost benefit analysis of participation in the 340B program using estimates of 340B prices. One respondent found participating would save money while two found no cost savings. Four others planned to conduct such an analysis in the future. For the 28 pharmacy directors who did not plan to complete an analysis, insufficient staff time and resources was the most frequently reported reason for not conducting an analysis (46%). Other reasons included inability to estimate 340B pricing (32%), not considering participation at this time (28%), and approximate amount of savings already known (7%).

Factors Influencing Participation

Pharmacy directors who knew they were eligible were asked to rate the level of importance of nine different factors that might influence their decisions to participate in

the 340B program. The nine factors were 1) expected cost savings, 2) record keeping requirements, 3) demands on staff time, 4) inventory maintenance, 5) utilization of high cost drugs, 6) concern about GPO discount, 7) impact on local pharmacies, 8) need for contract with local or state government, and 9) impact on hospital retail pharmacy. The first six factors were seen as being very important when considering participation in the program (Figure 1). The remaining factors were either not important or did not apply to a substantial number of respondents.

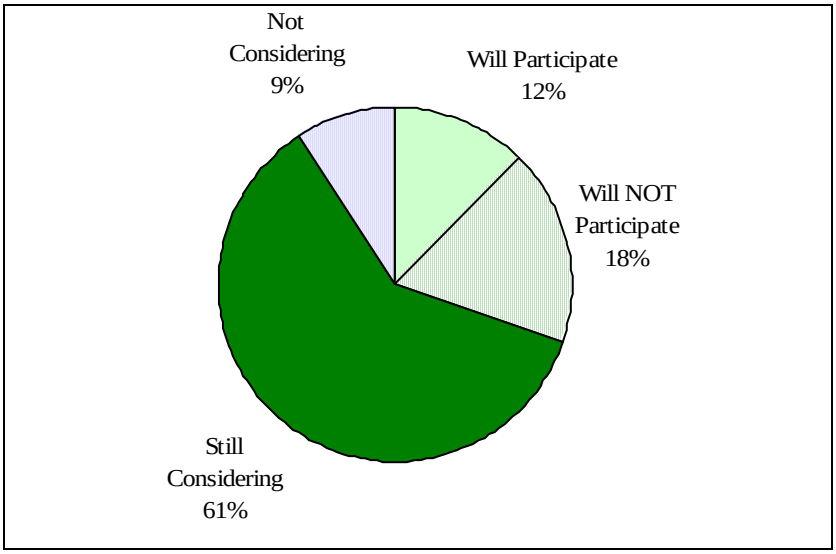
Figure 1: Importance of factors influencing participation (n = 35)



Decision on Participation

Pharmacy directors who knew they were eligible were asked to indicate their current position regarding participation in the 340B program. As illustrated in Figure 2, most are still considering the program and have not made a final decision.

Figure 2: Participation decisions (n = 35)



Discussion

The survey results show that awareness of the 340B Drug Pricing Program among pharmacy directors at eligible rural hospitals is still somewhat limited, with over half of the respondents unaware they were eligible to participate. Those who knew they were eligible to participate learned of this most often from hospital senior administrative staff or from their drug wholesaler. While comprehensive information on the 340B program is available from federal agencies, most notably the HRSA's Office of Pharmacy Affairs which administers the program, respondents relied instead on peers from other hospitals or staff within their own hospitals to learn more about the program. Based on the level of outstanding technical assistance needs, eligible rural hospitals do not seem to acquire all of the information they need to understand, evaluate, and implement the program. A solid understanding of the program is necessary to evaluate the expected cost savings and implementation requirements, which respondents reported were the most important factors when considering whether or not to participate in the 340B program. Eligible

hospitals also need assistance to overcome the perceived barriers of the program's record keeping requirements and demands on staff time.

Additional efforts are needed to ensure that rural hospital administrators are aware of their eligibility to participate in the 340B program. Targeted education and technical assistance would help to ensure that pharmacy directors and administrators understand the program and are able to make informed decisions about whether or not to participate.

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[1] Richardson, K. (nd) The Public Health Service (PHS) Section 340B Drug Pricing Program in basic language. HRSA Pharmacy Services Support Center.
[2] Powers Pyles Suter & Verville, PC. Eligibility of Rural Hospitals for the 340B Drug Discount Program. Public Hospital Pharmacy Coalition. Washington, DC: March 19, 2004.
[3] *See* Powers et al, note 2.
[4] Federal Register: October 25, 1996, Vol 61, No. 207, page 55157-55158, "(C) Definition of a Patient" ftp://ftp.hrsa.gov/bphc/pdf/opa/FR10241996.pdf, accessed January 3, 2007.
[5] Available at http://www.hrsa.gov/opa/dsh.htm, last accessed January 3, 2007.
[6] Available at http://opanet.hrsa.gov/opa/CE/CEExtract.aspx, last accessed January 3, 2007.